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Transmitted herewith for filing is the patent application of

Inventor(s): DANIEL R. DEAKTER

For: SYSTEM AND PROCESS FOR MATCHING PATIENTS WITH CLINICAL MEDICAL TRIALS

Enclosed are:

X Specification, Claims and Abstract *(20 pages)*
X Five (5) sheets of drawing(s)
__ An Assignment of the Invention to ^
X Assertion of Small Entity Status Under 37 CFR 1.9 and 37 CFR 1.27
X A Declaration and Power of Attorney for Patent Application

The filing fee has been calculated as shown below:

			Small Entity			Other Than A Small Entity	
For:	No.Filed	No.Extra	Rate	Fee	Or	Rate	Fee
Basic Fee				$375.00			$750.00
Total Claims	17-20	0	x9	$0.00		x18	$0.00
Indep Claims	2-3	0	x42	$0.00		x84	$0.00
Multiple Dep. Claim Presented			140			+280	
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__ Any filing fees under 37 CFR 1.16 for presentation of extra claims

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of)
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DANIEL R. DEAKTER)
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Serial No.)
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Filed)
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For SYSTEM AND PROCESS FOR)
MATCHING PATIENTS WITH)
CLINICAL MEDICAL TRIALS)
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Debbie Tingler, Sec'y to Andrew B. Morton

TRANSMITTAL SHEET

Enclosed are the following documents:

Specification, Claims and Abstract (20 pages)

Five (5) Sheets of Formal Drawings

Declaration and Power of Attorney

Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i)

Check in the Amount of $375.00 (filing fee)

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Respectfully submitted,

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SYSTEM AND PROCESS FOR MATCHING PATIENTS WITH CLINICAL MEDICAL TRIALS

Cross-Reference to Related Applications

This application is a continuation-in-part of application serial number 10/290,725 filed on November 8, 2002 and having the same title as the present application.

TECHNICAL FIELD

This invention relates generally to the field of clinical drug and device trials and more specifically to a process for obtaining patients for these trials and for pricing the value of the enrolled patients and processing payment to screening physicians and/or hospitals.

BACKGROUND ART

As the number of elderly people increase in the United States and their lifespans extend there is an ever increasing need for newer and safer pharmaceutical products. As such, there is a need for new drugs and medical devices to be approved more rapidly. With the mapping of the human genome it is estimated that drug targets and drugs will multiply tenfold, necessitating more clinical testing. In fact, The Pharmaceutical Research and Manufacturers of America (PhRMA) states that all drugs currently on the market are based on about 500 different targets. They expect this number to increase 600-2000%, to 3,000 to 10,000 drug targets in the coming years. However, such medical advances are outrageously expensive and have necessitated changes throughout the industry.

It is estimated to cost $900 million to bring one new drug to market. And it is estimated that the average pharmaceutical company has 70 new drugs in development. This has forced the pharmaceutical companies to consolidate for the purpose of underwriting the prohibitive expense of bringing a drug to market. The average drug takes 1 0 to 12 years to bring to market and must negotiate a series of 3 clinical trials before approval by the Food and Drug Administration (FDA) can even be granted, leaving 8 to 10 years on a drug patent to recoup costs and turn a profit. Factoring in the governmental and managed care cost

containment pressures, the pharmaceutical companies must produce one blockbuster medicine every 18 months to survive.

In summary, the pharmaceutical companies are in a position where they are producing more new drug compounds than ever before; they are about to lose the patents on many of their highly profitable, blockbuster, drugs; and they are being squeezed by the managed care industry. It is therefore critical for the pharmaceutical companies to discover, test and market the maximum number of new drugs in the minimum amount of time.

In order to speed up this process, business efficiencies are being applied to the previously haphazard clinical trials process. According to a Tufts University study, each day a study is late a pharmaceutical company can lose $ 1.3 million in lost prescription drug sales and it can be as high as $ 1 0 million for a blockbuster drug. Clinical trials are for the most part paper-based; necessarily cumbersome; and slow to monitor, process and store. One of the key factors affecting the time it takes to complete a clinical trial or study is the time it takes to recruit, screen and refer patients to the study. Only when the study is completely populated with patients can testing begin. Currently, the haphazard methods to recruit patients can take up to a year and 25% of the duration of the clinical study and thus, it becomes no surprise that 75% of all clinical studies are completed late.

There are a number of web-based clinical trial management software programs which plan, administer, and process trials for pharmaceutical companies. Although less than 15% of drug trials are e-clinical trials, this number is expected to increase to 50% or more in the next few years. Such trials will allow realtime monitoring of trials for adverse drug reactions and quality control, as well as more efficiently, move and process the prodigious amount of data generated. However, one area which still has not been adequately addressed is patient recruitment.

Traditionally, patients for studies have been enrolled from an investigator's clinic or practice, via referrals or by advertising. One prior art publication that addresses this problem using the internet, **Systems and Methods for Selecting and Recruiting Investigators and Subjects for Clinical Studies** Provisional Application No. 09923,385 by Leslie Dennis Michelson and Leonard Rosenberg utilizes an online web-based system to screen and enroll investigators and patients, and matches patients to an appropriated investigator by zipcode. Another prior art is entitled **Recruiting A Patient Into A Clinical Trial**, Pub. No.US

2002/0099570 A1 by Knight. Basically, Knight discloses how a patient with a particular disease may find a relevant study using a computer, a web browser and Internet connection. Otherwise, the need for recruiting patients is served by databases of patients available for drug trials, or by programs that flag key words on dictated summaries using a search engine for evaluation for eligibility in studies, or by web-based patient enrollment programs. There are a number of websites where patients may do a preliminary application for eligibility and thereby enroll by this means.

The known prior art does not utilize data as close to realtime as possible. It also does not systematically search all available places that patients may be found for drug trial enrollments. In particular, those websites that deal only with investigators comprise only 5% of all physicians, and a corresponding number of patients. Both Knight's and Michelson's methods does not systematically search for and find patients. It is believed that none of the known systems have a way to tap into and motivate the 95% of non-research performing physicians to find and enroll their patients into studies. And the known systems depend on patients having a computer with internet access. The method that searches dictations and flags patients is basically used in the offices of physicians with large practices who do research. These physicians are then paid for each patient inquiry found and for administering the study on that patient. However, these physicians are usually specialists who depend on referrals and it may take months for newly diagnosed patients to see the specialist.

Yet another difficulty in obtaining patients for clinical medical trials is that the Health Insurance Portability and Accountability Act of 1996 has very strict requirements as to transmission and use of patient information. Accordingly, although certain medical entities have extensive information regarding their patients and physicians, they are not permitted to share this information with other medical organizations such as drug manufacturers or medical device manufacturers.

Therefore, based upon the foregoing, there is a need for a process that will tap a larger pool of patients more systematically, and that will identify prospective patients at an earlier stage of their ailment before they see the appropriate specialist while maintaining their privacy. And there is also a need to accurately estimate the cost of doing the study and distribute payments to the participating physicians.

SUMMARY OF THE INVENTION

A system for enrolling patients in a medical study, comprising a database component operative to maintain a hospital database component and its plurality of hospital databases and their corresponding plurality of patients and medical records, and a clinical studies database component and their corresponding plurality of medical studies; a communications component to alert said hospitals of said medical studies and receive changes to said database components; and a processor programmed to update said database components; periodically match compatible hospital patients and medical studies; and generate reports to matched medical practices in said medical studies.

In light of the foregoing, it is a first object of the present invention to provide a system for screening, identifying and enrolling patients in a medical study, comprising: a database component operative to maintain a medical practice database component and their corresponding plurality of specialties and a clinical studies database component and their corresponding plurality of medical studies; a hospital database component and their corresponding plurality of patients, a communications component to alert said medical practices for eligible patients to said medical studies and observe changes to said database components; and a processor programmed to: update said database components: periodically match compatible medical specialties and medical studies; and generate reports to matched medical practices in said medical practice database.

It is another object of the present invention to provide a computerized method for matching patients to clinical medical studies, comprising: identifying a group of medical practices; identifying at least one clinical study; maintaining a database identifying each said medical practice and each said clinical study; and comparing said medical practices and said clinical studies and matching one to the other.

BRIEF DESCRIPTION OF THE DRAWINGS

For a complete understanding of the objects, techniques and structure of the invention, reference should be made to the following detailed description and accompanying drawings, wherein:

Figs. 1A and 1B are a schematic diagram of the system according to the present invention;

Fig. 2 is a flowchart of the process according to the present invention; and

Fig. 3 is a flowchart of the process used in determining a cost per patient enrolled in a clinical trial.

BEST MODE FOR CARRYING OUT THE INVENTION

Referring now to Figs. 1A & 1B, it can be seen that a system and related method for enrolling patients in a medical study is designated generally by the numeral 10. The system 10, includes various organizations or entities that cooperate with one another to enroll patients in a medical study, provide results of the study, and distribute payments for services rendered. In particular, the system 10 includes a pharmaceutical or medical device company (Sponsor) designated generally by the numeral 12. As discussed previously, pharmaceutical companies and medical device manufacturing companies are required to assure the consuming public that the drugs and/or devices that they manufacture are safe for use and/or consumption and that they have no adverse consequences resulting from their use. In order to obtain an independent evaluation of the drug or medical device, the pharmaceutical company 12 may contract with an entity identified by the initialism CSR 14. It will be appreciated that the pharmaceutical companies may contract a study for a particular drug or device with various CSRs and as such they are designated with an appropriate alphabetic suffix. A CSR 14 may be an entity such as a Contract Research Organization which procures drug trial contracts so that they can either perform the trials themselves, or outsource it; a Site Management Organization which manages multiple research sites, inasmuch as these organizations do research at multiple places or facilities; or a Researcher which may be an individual doctor or medical professional, either individually or in a group, that does research as a part of their professional medical services. Accordingly, a CSR may be any entity that does studies and hence has a need to recruit patients or subjects for these studies.

The sponsor 12 provides a raw study eligibility profile 18. As will be discussed in more detail later, a coordinator 30 modifies the information into an appropriate format which may be later used by the coordinator 30 and/or the CSR 14. It will be appreciated

that the CSR 14 could also receive the profile 18 directly from the sponsor 12 and in turn provide that information to the coordinator 30.

Another set of participants in the system 10 are medical practices designated generally by the numeral 20 wherein any number of specific medical practices are provided with an alphabetic suffix. For example, medical practice 20A may be a medical practice specializing in dermatology, while medical practice 20B maybe a medical practice specializing in cardiology. Likewise, medical practice 20Z may be a hospital practice that specializes in emergency medicine. Each medical practice 20 has associated therewith a patient clientele designated as 22 with a corresponding alphabetic suffix associated with the alphabetic suffixes of the medical practice 20. In addition some of the practices will admit patients to a hospital or send them for outpatient tests.

Another set of participants are hospitals which are designated by the numeral 21, wherein each specific hospital is designated by an alphabetic suffix. Each hospital 21 has associated therewith an identifier 23. The identifier 23 is an entity that consists of a communications component 24 capable of receiving and sending communications in any number of forms, including, but not limited to facsimile, page, email, voice text, website data entry and instant messaging. The identifier 23 includes a processor 25, which includes the necessary hardware, software and memory to assist the implementation of the system and its methodologies detailed herein. Additionally, the identifier 23 contains a database 26. The database 26 contains: a database of clinical study eligibility criteria 27 which includes necessary preconditions to be met before qualifying for a study, a database of patients 28 and their clinical and demographic information which is a duplicate of the hospital database, and a database of physicians 29. The study eligibility database 27 is set-up in a predetermined format by the coordinator 30 to facilitate the searching and matching of patients to particular drug/device evaluations.

The CSR 14 may be requested to evaluate a drug or device, which is designated in the drawings as D/D, wherein different drugs or devices are provided with a different alphabetic suffix as deemed appropriate by the CSR 14. The sponsor 12, alone or in conjunction with the CSR 14, prepares the study profile 18. As will be discussed in further detail, the study protocols, which contain eligibility criteria, are submitted to a coordinator designated generally by the numeral 30. If desired, the pharmaceutical company sponsor 12 may directly establish a relationship with the coordinator 30 for the purpose of obtaining

prospective patients for a clinical study, and/or performing the study. In the alternative, the CSR 14 and coordinator 30 may agree to provide their collective services to the sponsor 12.

The coordinator 30 is an entity that assists the sponsors 12 and their CSRs 14 in finding patients that meet the eligibility requirements established by the sponsor for the drug or device 16. In a manner much like the identifier 23, the coordinator 30 is capable of receiving and sending communications in any number on forms, including, but not limited to facsimile, page, email, voice text, website data entry and instant messaging. The coordinator 30 includes a computer processor 32 which includes the necessary hardware, software and memory to implement the system- and methodologies disclosed herein. The processor 32 is programmed to coordinate all activities of the system such as routing messages, performing searches generating billing statements and facilitating the clinical study process. Moreover, the processor 32 provides access to a database designated generally by the numeral 36. The processor 32 also formats the contents of the database and allows for changes, additions, or deletions to the database records as needed. As will be discussed in further detail, the database 36 has several database components including, but not limited to, a clinical study database component 38, a medical practice database component 40, a patient database component 42, a doctor's fees database component 44, an ancillary fees database component 45, a CSR database component 46, a sponsor database 47 and a hospital database 49. All the database components are readily accessible by the processor and are searchable by key words or as deemed appropriate. The processor 32 also provides a communications component 48 which allows for direct electronic or voice communications between the CSR 14, the medical practices 20 or hospital 21, and the coordinator 30 and the identifier. The database 36 is structured to efficiently allow for the searching of various data attributable to the patients 22, the medical practices 20 and the clinical study eligibility requirements associated with a particular drug or device 16.

The communications components 24 and 48 allow for the transfer of database information between the identifier 23 and the coordinator 30 and otherwise facilitate the communications between the various components of the system 10. In particular, the study criteria database components 27 and 38 may be interchanged between entities. The study database component 38 will be derived from the eligibility criteria profile 18. And the study criteria database component 38 will be formatted in a manner similar to component 27. Indeed, it is envisioned that the component 38 will be exported to the identifiers 23 to allow

medical staff associated with the hospitals to find studies that may be helpful to their patients. The transfer of data of the physician's database component 29 and database component is relatively unfettered. However, information in the patient database component 28 remains with the respective identifier in view of federal privacy regulations. But it will be appreciated that specific identifying information might be parsed from the component 28 to allow for export and searching of potential candidates for consideration as a candidate for a particular study.

The clinical study profiles 18 that are loaded into the database component 38 may include, but are not limited to, the age and gender of the prospective patients, their height, weight, genetic characteristics including specific DNA samples or markers, blood pressure ranges, blood sugar levels, and the like. The doctor database component 40 includes, but is not limited to, the practice areas of the doctor or hospital, the number of patients in their practice, the location of their practice and the like. The patient database component 42 includes general, non-identifying, information about all of the patients associated with a particular medical practice 20 or hospital 21 and may include their specific height, weight, age, any particular genetic markers or the like. A code may be used to anonymously identify each patient in the database, wherein only selected personnel have access to the codes. Database component 42 may include key words associated with a patient's medical history including dictations prepared by the medical professional; lab, radiology and pathological reports; blood work panels and other appropriate information. The database component 44 includes medical fees associated with relatively standard procedures that are performed by the medical professional such as blood tests, office visits, taking of vital signs, supervising and preparing a specific type of medical history, performing a medical physical and the like. The ancillary fee database component 46 is associated with preparation of reports and other activities by personnel within the doctor's office 20 or 21, mailing charges and the like. The CSR database component 47 would keep an accounting for the coordinator 30 of which CSRs received which patients and how much the CSR has paid to the coordinator. The sponsor database 47 would keep an accounting of sponsors and payments from each sponsor.

At least one personal computer 50 may be linked to the coordinator 30 to allow for searching of the various database components and linking to other computers on a network or the internet. Of course, each identifier processor 25 may be linked to a respective

personal computer 51 to allow for on-site searching of studies or patients at the hospital, or allow linking to the coordinator 30 and searching of the database 36.

Referring now to Fig. 2, the process which is used in implementing the system 10 is designated generally by the numeral 100. The process 100 utilizes the following steps for matching patients to clinical studies. In particular, at step 102, the database inputs are made to the coordinator 30. In particular, the information regarding the medical practice 20, the patients 22A, the doctor fees and the ancillary fees are submitted to the processor 32 for loading into the database 36. Similar database inputs are made to the coordinator 30 from the hospitals 21 including doctor information and selected patient information. And, the CSR 14, or the sponsor 12, inputs to the database the study criteria eligibility 18 and related information proffered by the pharmaceutical company and/or the CSR.

In order to properly understand the relationships between the primary entities, a brief review of these relationships will be discussed. As noted previously, the sponsor 12 needs to obtain test data regarding their respective drugs or devices D/D to comply with Food and Drug Administration regulations and to assure the general consuming public that the new drugs or devices which they have developed are safe for use. Accordingly, in exchange for test data obtained by these clinical studies, pharmaceutical companies and device manufacturers (sponsor 12) will pay a predetermined amount of money to a CSR 14, or to the coordinator 30. These costs are based upon estimates generated at step 104 that the coordinator 30 makes based on the visit/procedure requirements of the study protocols that are detailed herein. At step 104, the coordinator 30 generates an estimate per patient derived from the database components inputs provided previously by the medical practices, the proposed study protocols, and a percentage mark-up for the coordinator. Accordingly, if the estimate is within the budget of the pharmaceutical company, the sponsor 12 or CSR 14 in turn will contract with the coordinator 30 for them to provide the patients for the study.

Upon completion of step 106, several methodologies may be employed for obtaining the necessary patients for the study requested by the sponsor. In the preferred embodiment, the coordinator 30 transmits at step 108 the eligibility criteria to the identifier 23 of each contracted hospital to search the hospital database at step 112. In other words, the coordinator 30 will have pre-established relationships with the hospitals to allow the coordinator to search the respective patient database 28 as well as their own patient database 48. Of course, staff within each hospital could utilize their computer 51 to undertake a

search of available studies. In an alternative embodiment, the identifier's functions could be duplicated by the coordinator. In any case, a report is then generated at step 114, wherein the identifier 23 matches the study information eligibility requirements in database component 27 and/or database component 38 with the patient database component 28 or 42. In particular, the matching report will also include the name of the patient (or anonymous code) that potentially fulfills the requirements of the study requested by the sponsor, the name of the study he/she is qualified for, a list all of the eligibility criteria they meet and their values and the patient's treating doctor of record or alternate. And this report will be sent directly to that doctor or medical practitioner. There will be a report for each patient, however, alternatively, these can be batched together and sent to the physician. At step 116, the treating contracted physician of record approaches his or her prospective patients, apprises them that they are eligible for a study and obtains their consent, if they agree, to forward their relevant medical information to the coordinator 30 or they may then contact the coordinator 30, directly and submit their medical information via the communications component 48 associated with the processor 32.

In another alternative, a medical practitioner, who may or may not be part of a medical practice included in the database component 40, may search the coordinator's website, at step 118, by inputting particular search words that afflict a particular patient that medical practitioner may know of. At step 120, the medical practitioner screens and flags the studies that may be of assistance to their particular patient and contacts the coordinator 30. This may be done manually by reviewing a listing of the searches or it may be done automatically by inputting key words. Or the medical practitioner may search his own practice manually or with an internally maintained search engine to obtain and submit a patient referral to the coordinator.

In any event, at step 116 the medical practices 20 or the hospitals 21 confirm the data obtained on the identified candidate and contacts the prospective patient candidate. At step 124 the physician counsels and obtains the consent of the prospective patients to affirm that they match the criteria requested by the sponsor and to obtain all the necessary release forms from the patients so that they understand the risks and potential benefits of being part of the study. These steps are necessary to preserve patient privacy and to conform with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). At step 126, the processor 32 matches the patients with the CSR 14 and selects the best available

patients that meet the eligibility criteria. Upon completion of step 126 the appropriate data is sent at step 130 to the CSR 14 utilizing the communications components 24 and/or 48 and upon receipt of the appropriate number of patients for the study, the study is commenced. At step 132 the CSR informs the coordinator 30 of all of the patients that were enrolled.

At step 134, the study is initiated and the coordinator 30 calculates and confirms a study cost based on the price per patient, estimated earlier at 110, for performing all the necessary office visits to obtain the necessary reports resulting from the various procedures such as blood screening and testing, dispensing of the medication to be evaluated, or the device to be analyzed. Also included in the calculation of the costs are stipends for the patients and any related secretarial or office visit charges and the number of eligibility criteria. Once these procedures are performed, the number of patients enrolled at step 132 are multiplied by the price per patient and the costs are submitted, a bill is generated, at step 136, by the coordinator 30 and sent to the appropriate sponsor or CSR 16.

At step 138 the sponsor 12 or CSR 14 will pay the coordinator 30 the appropriate amount and at step 140 the coordinator 30 takes a certain percentage of the payment to cover their costs associated for maintaining the processor and the database information, and the remaining funds are paid to the appropriate medical practice and or hospital to cover their costs.

Referring now to Fig. 3 of the drawings and to the Example below, a detailed explanation of the process steps designated by the numeral 200, that are required prior to the cost calculation step 134 will be discussed in detail. At step 240 the number of visits, specific procedures and number of eligibility criteria to be performed in a particular study is input into a calculator maintained by the processor. Subsequently, at step 242, the processor accesses the doctor fee database and at step 244, calculates a doctor fee for a particular study. At step 246 the processor accesses the ancillary fee database for the same study and calculates the ancillary fees at step 248. At step 250 the calculated fees are summed to generate a total dollar value for the study. The following steps are provided with × suffixes, e.g. 134× ; to indicate that they are related to the same corresponding number steps shown in Fig.2 but are provided with more information. At step 134× the number of patients enrolled in the study are input and various other factors may be applied according to the location of the medical practice and various cost differentiations that may occur,

especially if the studies are conducted on a national level and a cost for the study is generated, then divided by the number of patients needed in the protocol to generate a cost per patient enrolled. Afterwards, the coordinator generates a bill at step 136× that is submitted to the sponsor or CSR. As discussed previously, upon payment of the bill by the CSR, the appropriate funds are distributed between the various medical practices, the patients and the coordinator 30.

EXAMPLE

Study Visit		1	2	3	4
Study Week		2	4	6	8
Informed Consent		X			
Medical History		X			
Physical Examination		X			
Vital Signs		X	X	X	X
Electrocardiogram		X	X		
Fasting Blood Specimen		X	X		
Pregnancy Test		X			
24-Holter Monitor			X	X	
Study Medications Given to Patient			X	X	
Adverse Event Assessment			X	X	X

Calculate patient-visit fees:

VISIT ONE

	Done by the physician	$125
Medical Physical	Done by the physician	$125
Assistant Time	Vital Signs, secure the informed consent,etc.Can be done by Physician's Assistant, Nurse Practitioner or Nurse	$75
Electrocardiogram		$100
Blood Draw	Assumes a protocol requiring the blood sample to be shipped to a central laboratory. Additional fees apply if the site sends the blood draw to its own laboratory	$25
Pregnancy Screen	Urine pregnancy test in office with testing material supplied by the sponsor	$25
Additional Charges	Office visit	$100
	Secretarial charge for visit	$25
	Patient Stipend	$35
Total charges for visit one		$575

VISIT TWO

Assistant's fees	Add $25 for Physician if done by Physician	$100
Visit		$100
Secretary		$25

24 hour Holter Monitor	Sponsor Supplies the monitor. $200 reflects the time it will take the research coordinator to apply the instrument and instruct the patient	$200
Patient Stipend	The higher stipend for this visit is due to the requirement that the patient wear the monitor, which is uncomfortable for 24 hours	$150
Total Charges for Visit two		$575

VISIT THREE

The requirements for visit three are the same as for visit two.

Total Charges for Visit		$575

VISIT FOUR

Physical		$100
Electrocardiogram		$100
Assistant's fees		$75
Office Visit		$75
Secretary		$25
Patient Stipend		$35
Total Charges for Visit four		$435

Total per-patient fees for the four-visit study:

Visit one	.....	$635
Visit two	.....	$575
Visit three	.....	$575
Visit four	.....	$435
Total	.....	$2,220
$2250 per patient times 16	Enrollment called for 16 patients	$35,520
15% Overhead	.....	$5,328
IRB [Institutional Review	.....	$1,500
Advertising Allowances	.....	$1,200
Total	.....	$43,548

Taking the total of the studies $1,200 is subtracted out in advertising and calculate 20% of $42,348 which is $8,469.60. Divide this by 16 (for 16 patients in this study comes out to $529.35 per patient. As can be seen, studies which require more office visits and procedures are more costly. The Institutional Review Board and 15% overhead are usual fees and should be calculated into the total to make sure the study is profitable for the medical practice so as to encourage them to participate in the system 10.

Referring now to Figure 4, the sub-process designated by the numeral 300 commences at step 132 wherein the CSR informs the coordinator 30 of the identities and number of the patients enrolled for a specific study. This is instantaneously input into the database 36 at step 302. Next, at step 306 the coordinator sends the list of enrollees/study to the identifier 23 of the originating hospital 21. It will be appreciated that this information may be sent to multiple hospitals and their respective identifiers, depending upon whether a patient of a particular hospital is selected for a particular study. And the coordinator 30 provides a listing to the identifier of each patient enrolled from that location of the various times such as the time the patient information and consent are received by the coordinator 30, the time a match to a CSR 14 is made and the time that the candidate/consent/qualifying information packet is sent to the matched CSR 14. The identifier 23 generates a list of doctors with their corresponding list of de-identified patients (patient listings that have had their particular identifying information removed so as to protect their privacy), and a list of time stamps for various steps of their part of the process at 308. The identifier 23 generated list also includes the number of patients identified for that physician and the number of referrals made. At 310 that list is sent to the back to the coordinator 30, and at 312 a time stamped metric is generated for each doctor/patient and averaged for the study. The metric is a list of the various steps of the process and their mean times and standard deviations. The metric will necessarily include a mean plus standard deviation for completion of the process one patient. Thus the metric will serve as a basis for comparison the expected time of enrollment of all patients versus the enrollment targets currently used which can be six months or more. At 314 the metric is sent to the Sponsor and/or CSR for feedback. The metric provides information regarding the progress of the study and any preliminary data that may be useful to the sponsor. It will also facilitate estimated pricing for future studies based upon the number of criteria per study. For example, a study with six eiligibility criteria should be cheaper and simpler to complete than a study with twenty eligibility criteria. This data may also be used to find areas in any given study which can be made more efficient.

Based upon the foregoing, the advantages of the present invention are readily apparent. In particular, the system and related methods describe an automated process for identifying the patients and pricing their participation in the study accordingly. The system and methods also facilitate the rapid identification and enrollment of patients in studies and

provide for a way to obtain payment for the services rendered. The primary advantage of such a system is that it will be able to draw from the practices of a vast number of physicians and hospitals who are not currently involved in research and have no organized way to help patients who desire the latest medications and devices when all other alternatives have been exhausted. Accordingly, the present invention vastly widens the pool of available patients for studies, improves the accuracy of the study, and reduces the overall cost of providing a study inasmuch as an adequate number of qualified patients are quickly found for the study so that the study may be implemented on a timely basis. The present invention also provides an organized and rapid method to automatically enroll patients which helps the pharmaceutical company streamline their clinical trial processes. Moreover, the present invention is advantageous inasmuch as the pharmaceutical companies have exposed a wider number of hospitals or medical practices to the potential new drugs or devices which they manufacture and this helps their marketing campaign if the drug or device is ultimately approved. Yet another advantage of the present invention is that it fully utilizes the patient clientele of hospitals that might not otherwise be available to a study coordinator 30. And specific privacy safeguards may be put in place by the hospitals so that the confidentiality of patient information is maintained in compliance with HIPAA.

While the invention has been described in connection with a preferred embodiment, it is not intended to limit the scope of the invention to the particular form or methodology set forth, but it is intended to cover such alternatives, modifications, and equivalence as may be included within the spirit and scope of the invention as defined by the attached claims.

What is claimed is:

1. A system for enrolling patients in a medical study, comprising:

a database component operative to maintain a hospital database component and its plurality of hospital databases and their corresponding plurality of patients and medical records, and a clinical studies database component and their corresponding plurality of medical studies;

a communications component to alert said hospitals to said medical studies and receive changes to said database components; and

a processor programmed to:

update said database components;

periodically match compatible hospital patients and medical studies; and

generate reports to matched medical practices in said medical studies.

2. The system according to claim 1, further comprising:

said database component operative to maintain a medical practice database component identifying patients associated with each said medical practice in said medical practice database component;

said processor programmed to:

update said patient database component with data supplied by said medical practice or said hospital database component; and

generate reports to said matched medical practices to include a listing of prospective patients.

3. The system according to claim 1, further comprising;

a searching component for searching said clinical studies database; wherein said communications component is adaptable to receive queries from and query to said medical practices and hospitals via said searching components.

4. The system according to claim 2, further comprising:

said database component operative to maintain a fee database component identifying fees associated with procedures performed by medical specialties;

said processor programmed to calculate a total fee to be paid to each said medical practice and each said hospital participating in each said medical study utilizing said fee database component.

5. The system according to claim 4, further comprising:

said fee database component operative to maintain a doctor's fee database component identifying fees associated with doctor's procedures as part of said medical studies and an ancillary fee database component identifying fees associated with miscellaneous charges associated with said medical studies; said processor programmed to calculate said total fee from said doctor's fee database component and said ancillary fee database component.

6. The system according to claim 5, wherein said processor is programmed to generate a billing statement based upon said total fee and a number of patients actually enrolled in one of said plurality of medical studies.

7. The system according to claim 2, wherein said processor is programmed to generate a metric of completed components of the medical study

8. A computerized method for matching patients to clinical medical studies, comprising:

identifying a hospital;

identifying at least one clinical study;

maintaining a database identifying each said hospital and each said clinical study; and

comparing said hospital and said clinical studies and matching one to the other.

9. The method according to claim 8, further comprising:

maintaining said database to include a plurality of patient profiles associated with each said hospital; and notifying said hospital of said patient profiles that match the requirements of said clinical studies.

10. The method according to claim 9, further comprising:

confirming participation of a patient matched in said notifying step in one of said clinical studies.

11. The method according to claim 10, further comprising:

maintaining on said database costs incurred by each said medical practice in performing procedures specified by said clinical study; and

calculating a cost for performing said clinical study.

12. The method according to claim 11, further comprising:

generating and sending a billing statement to an entity responsible for initiating said clinical study.

13. The method according to claim 10, further comprising:

maintaining on said database doctor costs and ancillary costs incurred by said hospital in performing procedures specified by said clinical studies;

calculating a cost for coordinating and performing said clinical studies;

generating and sending a billing statement to entities responsible for initiating said clinical studies; and

determining a percentage of costs attributable to a coordinator and to said hospitals performing said clinical studies.

14. The method according to claim 9, further comprising:

maintaining on said database costs for performing procedures typically specified by said clinical studies;

inputting to said database procedures required by said clinical studies; and

estimating a cost for implementing said clinical studies.

15. The method according to claim 8, further comprising:

posting said at least one clinical study on a network accessible computer for review by prospective medical practices and prospective hospitals; and

communicating interest by said prospective hospitals and said prospective patients to a coordinator.

16. The method according to claim 8, further comprising:

searching on a network accessible by prospective hospitals; and

communicating interest by said prospective medical practices to a coordinator.

17. The method according to claim 9, further comprising:

generating a time deadline for performing procedures typically specified by said clinical studies;

inputting a completion date for said procedure; and

generating a metric report comparing said completion dates with said time deadlines.

ABSTRACT OF THE DISCLOSURE

A system and method for enrolling patients into a medical study, includes: a database component operative to maintain a medical practice database component and their corresponding plurality of specialties and a clinical studies database component and their corresponding plurality of medical studies. The system further includes a communications component to alert the medical practices of the medical studies and observe changes to the database components. The system also includes a processor programmed to update the database components, periodically match compatible medical specialties with the medical studies, and generate reports of the matched medical practices in the medical practice database. The system also includes a fee database component which the processor uses to calculate a fee for conducting the study.

Attorney Docket No. DKT.P.US0001A PATENT

COMBINED DECLARATION AND POWER OF ATTORNEY

Comment: UPDATED 12/1/00

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SYSTEM AND PROCESS FOR MATCHING PATIENTS WITH CLINICAL MEDICAL TRIALS

the specification of which

X is attached hereto.

____ was filed on _____ as Application Serial No. _____ and was amended on _____.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, ' 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, ' ' 119(a)-(d) of any foreign application(s) for patent or inventor=s certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor=s certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. ' 119(A)-(D)

Country (or indicate of PCT)	Application No.	Date of Filing (day, month, year)	Priority Claimed Under 37 USC 119
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

JUL. 11 2003 04:21PM P2/4 FAX NO. :5613619926 FROM: ANNE DEAKTER

Attorney Docket No. DKT.P.US0001A PATENT

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. ' 119(e))

I hereby claim the benefit under Title 35, United States Code, ' 119(e) of any United States provisional application(s) listed below:

Provisional Application Number	Filing Date

English Language Declaration

I hereby claim the benefit under Title 35, United States Code, ' 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, ' 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, ' 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

10/290,725	November 8, 2002	Pending
Application Ser. No.	Filing Date	Status

Application Ser. No.	Filing Date	Status

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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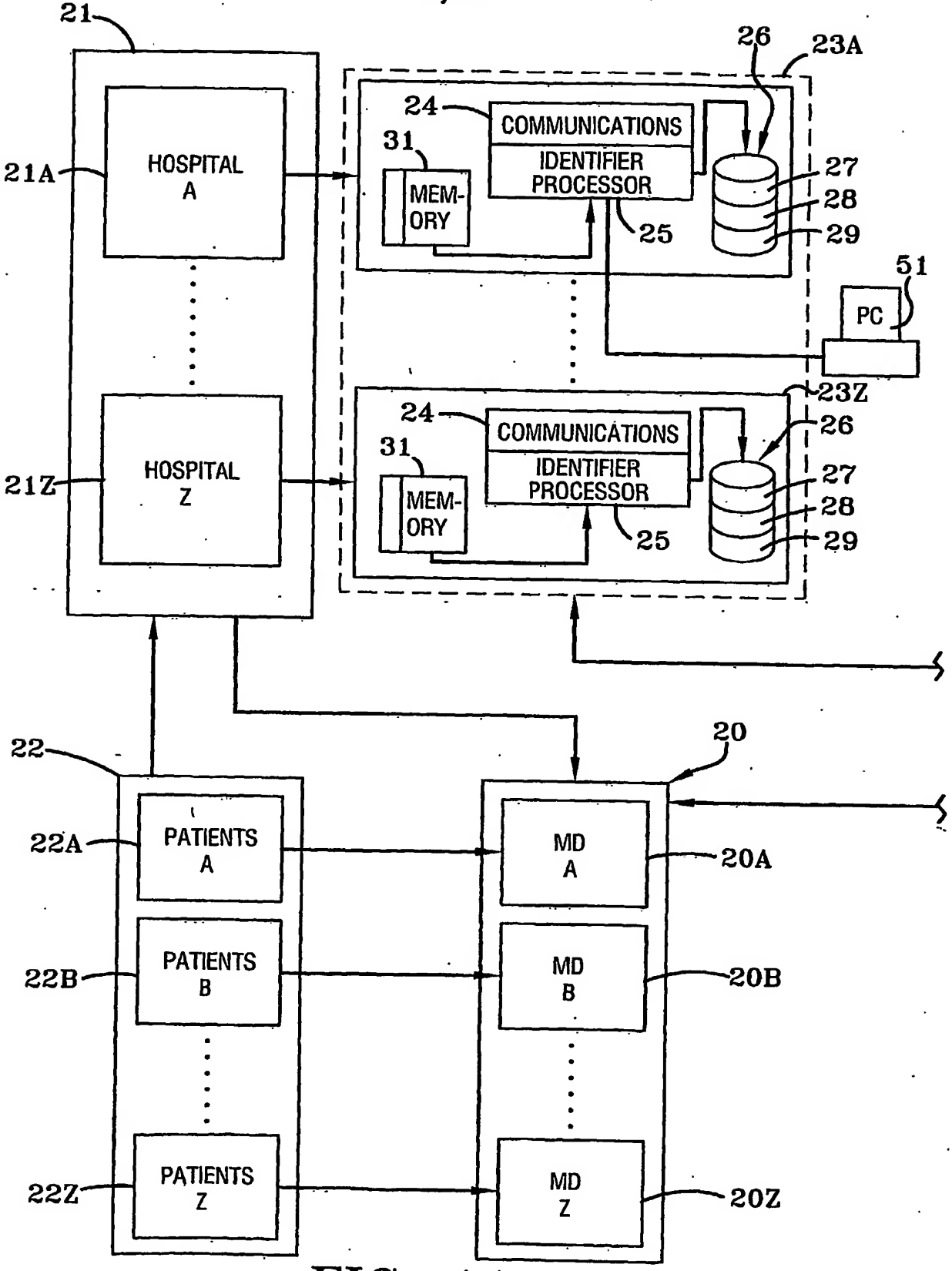
21
21A
HOSPITAL A
21Z
HOSPITAL Z
23A
26
24
COMMUNICATIONS
IDENTIFIER PROCESSOR
31
MEM-ORY
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27
28
29
51
PC
23Z
22
22A
PATIENTS A
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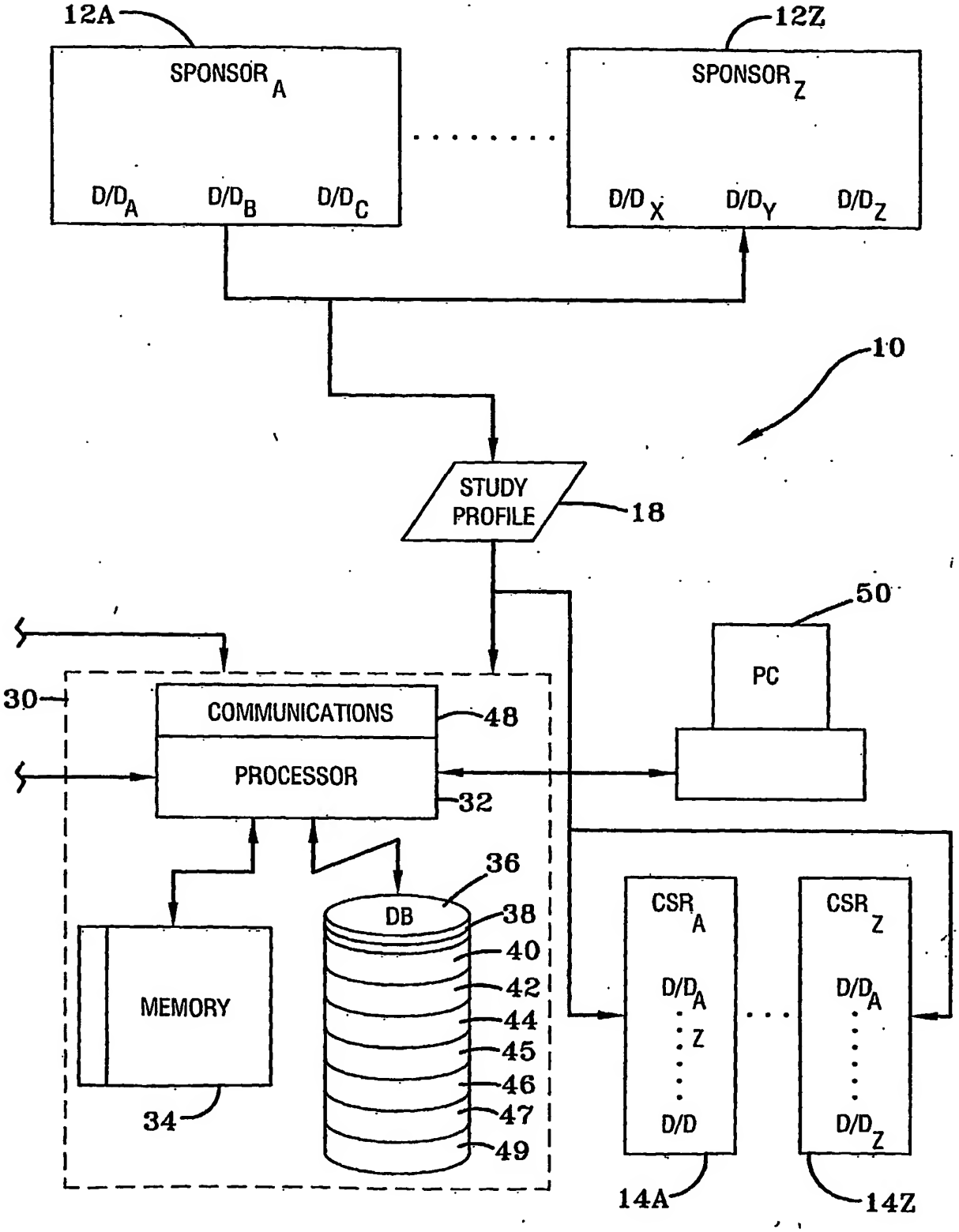
FIG-1A

2/5


12A
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D/D A
D/D B
D/D C
12Z
SPONSOR Z
D/D X
D/D Y
D/D Z
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STUDY PROFILE
18
50
PC
30
COMMUNICATIONS
48
PROCESSOR
32
36
DB
38
40
42
44
45
46
47
49
MEMORY
34
CSR A
D/D A
Z
D/D
CSR Z
D/D A
D/D Z
14A
14Z

FIG-1B

3/5

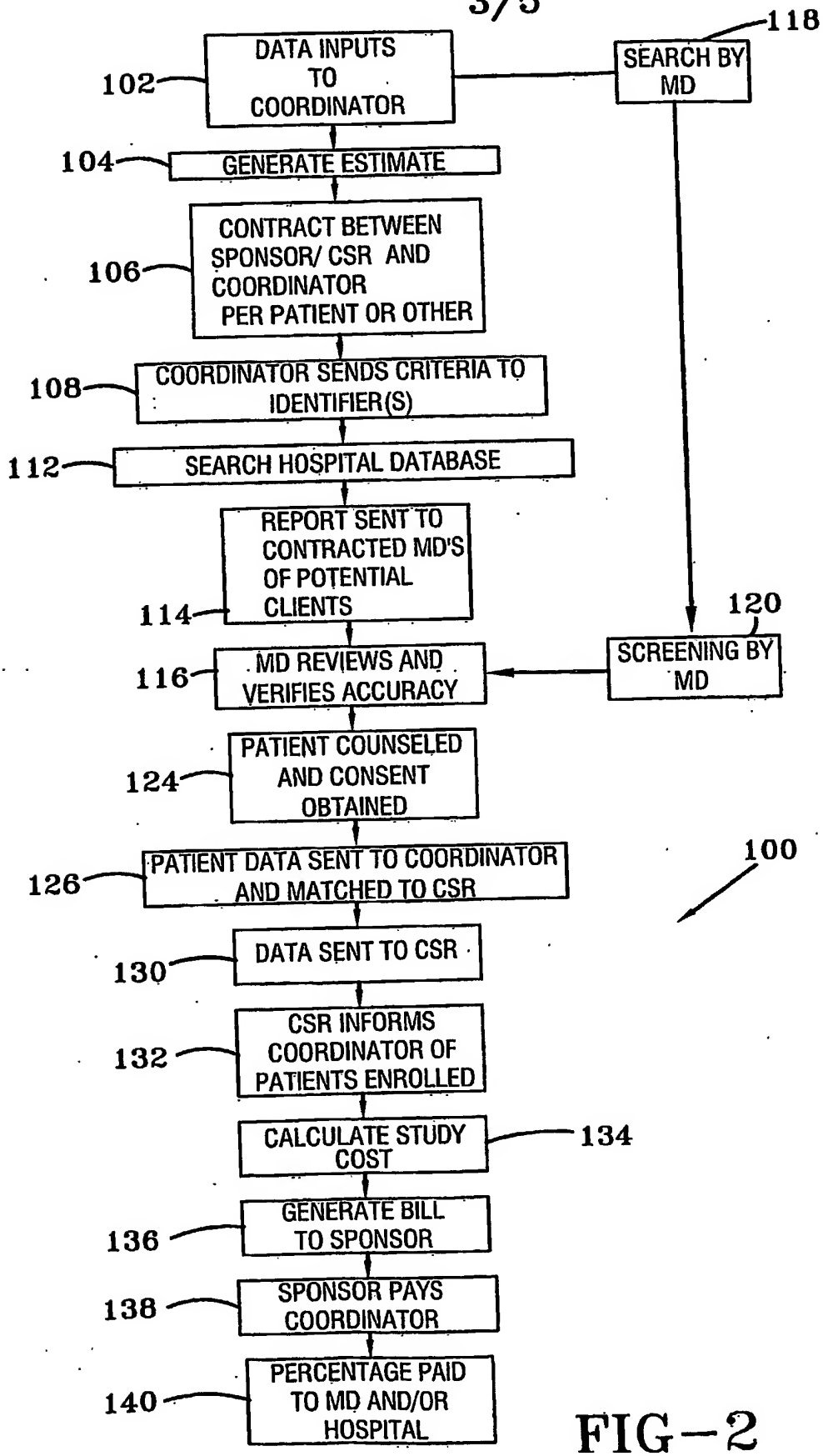

DATA INPUTS TO COORDINATOR
102
SEARCH BY MD
118
GENERATE ESTIMATE
104
CONTRACT BETWEEN SPONSOR/ CSR AND COORDINATOR PER PATIENT OR OTHER
106
COORDINATOR SENDS CRITERIA TO IDENTIFIER(S)
108
SEARCH HOSPITAL DATABASE
112
REPORT SENT TO CONTRACTED MD'S OF POTENTIAL CLIENTS
114
120
SCREENING BY MD
MD REVIEWS AND VERIFIES ACCURACY
116
PATIENT COUNSELED AND CONSENT OBTAINED
124
PATIENT DATA SENT TO COORDINATOR AND MATCHED TO CSR
126
100
DATA SENT TO CSR
130
CSR INFORMS COORDINATOR OF PATIENTS ENROLLED
132
CALCULATE STUDY COST
134
GENERATE BILL TO SPONSOR
136
SPONSOR PAYS COORDINATOR
138
PERCENTAGE PAID TO MD AND/OR HOSPITAL
140

FIG-2

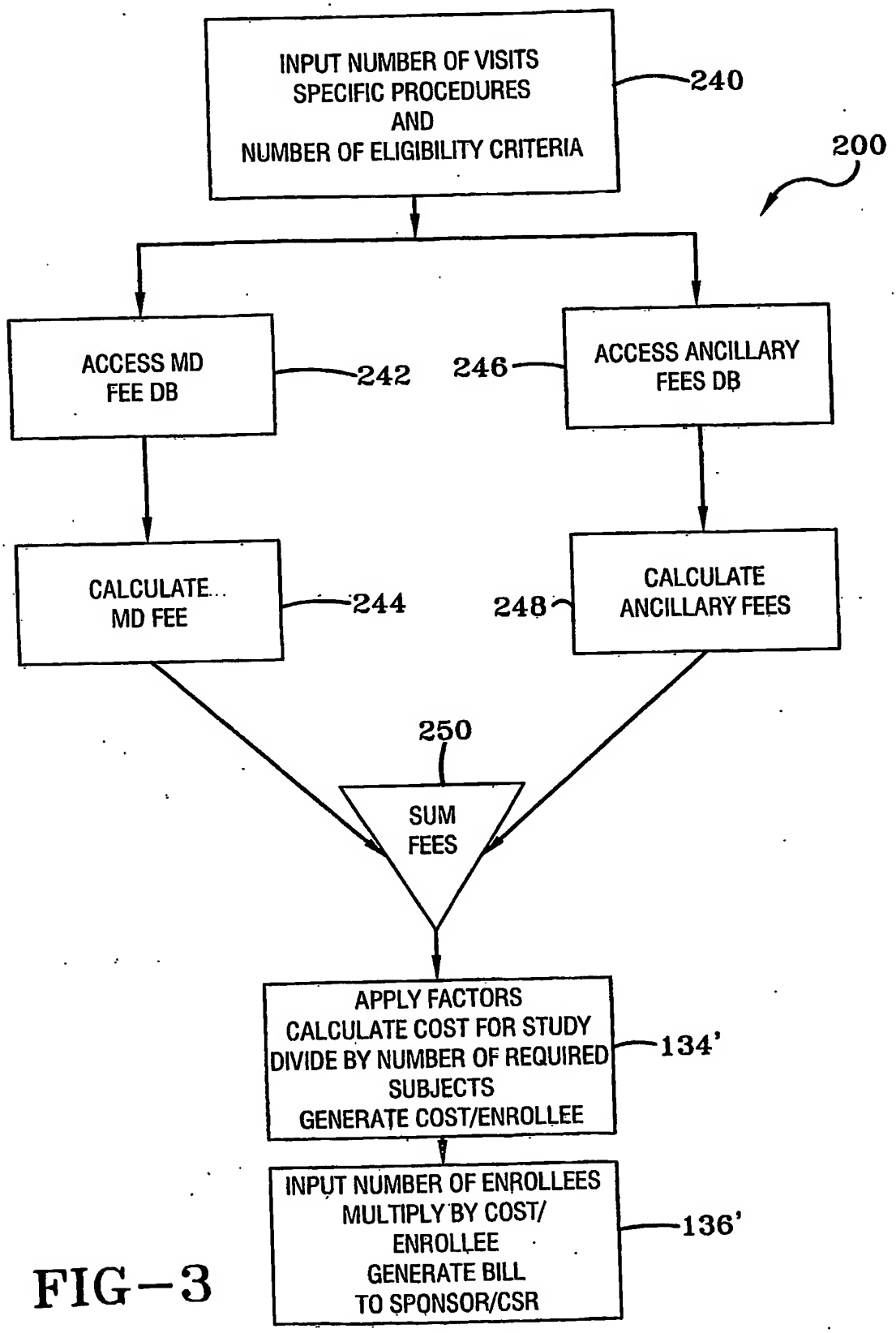
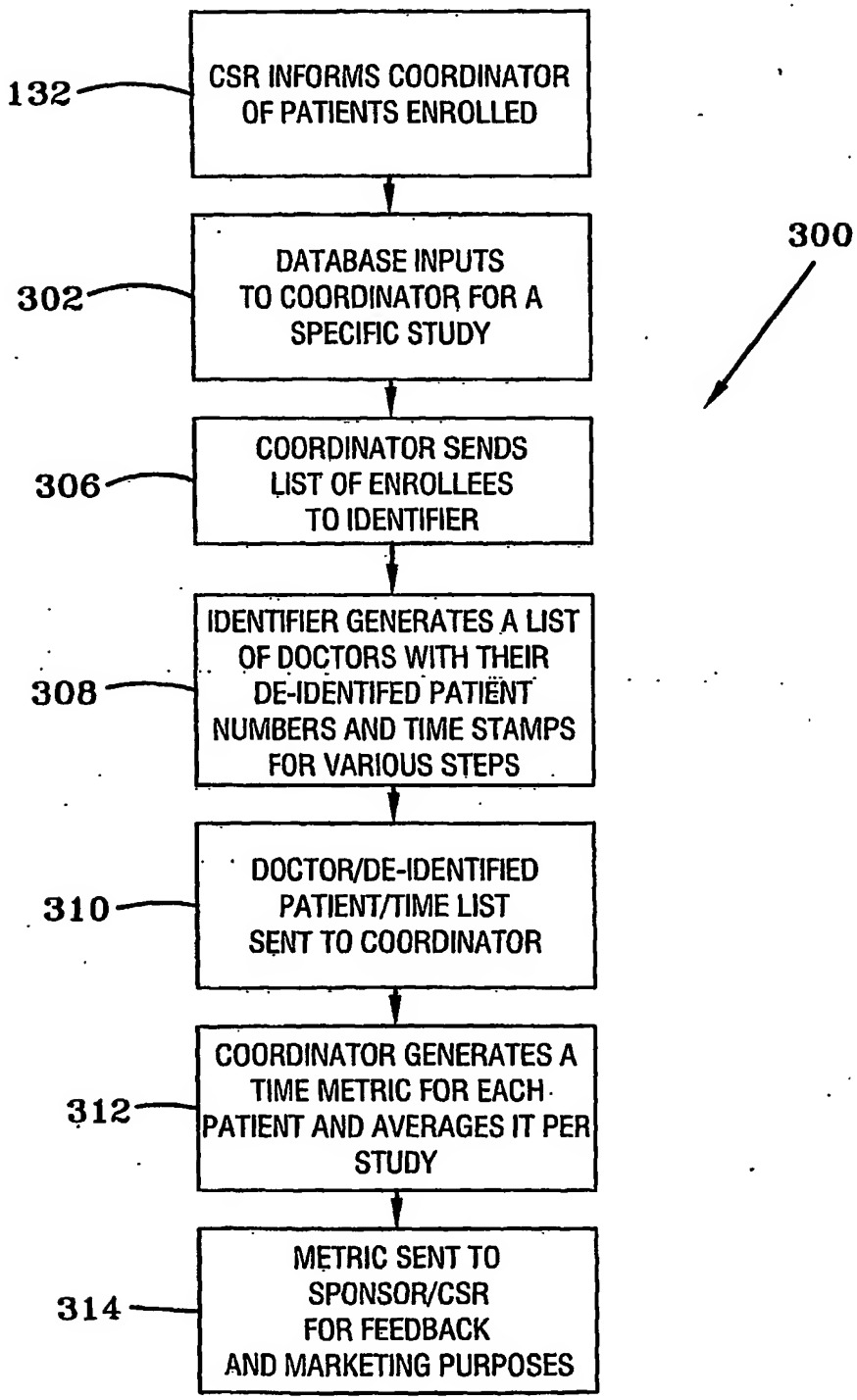

INPUT NUMBER OF VISITS
SPECIFIC PROCEDURES
AND
NUMBER OF ELIGIBILITY CRITERIA
240
200
ACCESS MD
FEE DB
242
246
ACCESS ANCILLARY
FEES DB
CALCULATE
MD FEE
244
248
CALCULATE
ANCILLARY FEES
250
SUM
FEES
APPLY FACTORS
CALCULATE COST FOR STUDY
DIVIDE BY NUMBER OF REQUIRED
SUBJECTS
GENERATE COST/ENROLLEE
134'
INPUT NUMBER OF ENROLLEES
MULTIPLY BY COST/
ENROLLEE
GENERATE BILL
TO SPONSOR/CSR
136'

FIG-3


132
CSR INFORMS COORDINATOR OF PATIENTS ENROLLED
300
302
DATABASE INPUTS TO COORDINATOR FOR A SPECIFIC STUDY
306
COORDINATOR SENDS LIST OF ENROLLEES TO IDENTIFIER
308
IDENTIFIER GENERATES A LIST OF DOCTORS WITH THEIR DE-IDENTIFED PATIENT NUMBERS AND TIME STAMPS FOR VARIOUS STEPS
310
DOCTOR/DE-IDENTIFIED PATIENT/TIME LIST SENT TO COORDINATOR
312
COORDINATOR GENERATES A TIME METRIC FOR EACH PATIENT AND AVERAGES IT PER STUDY
314
METRIC SENT TO SPONSOR/CSR FOR FEEDBACK AND MARKETING PURPOSES

FIG–4

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